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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,497	02/26/2004	Robert Bals	68004167.1001	4981

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PATENT DEPARTMENT
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EXAMINER

SPECTOR, LORRAINE

ART UNIT

PAPER NUMBER

1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.:

10/787,497

Applicant(s)

BALS ET AL.

Examiner

Lorraine Spector, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a pharmaceutical composition, classified in class 530, subclass 300.
- II. Claims 2-8, drawn to methods of increasing angiogenesis, classified in class 514, subclass 12.
- III. Claims 9-18, drawn to methods of decreasing angiogenesis, classification dependent upon species.
- IV. Claims 19-20, drawn to a method of altering the specificity of the peptide, classified in class 435, subclass 440.

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to each of inventions II and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the peptide can be used in either of the distinct processes, or for other uses, such as the generation of antibodies. Further, a search for the peptide will not reveal art as to the distinct methods of use, such that search of all three inventions would be an undue burden. Accordingly, restriction is proper.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II-IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Inventions II and IV use a common product, however the method steps, starting points and outcomes are completely different, and would require divergent searches. Invention III uses a group of products that are mutually

Art Unit: 1647

exclusive of the product used in Inventions II and IV, and thus is distinct and requires a separate search. Therefore, a search and examination of all three methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, the classification is different, and the subject matter is divergent.

Invention III is unrelated to Invention I, wherein the product of Invention I is neither made by nor used in the methods of Invention III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

In addition to the above restriction, the following species elections are required:

1) If applicant elects Invention II:

This application contains claims directed to the following patentably distinct species: (a) atherosclerosis, coronary heart disease, and arterial occlusive disease, (b) stroke, (c) ulcer and (d) wound. The species are independent or distinct because they are distinct medical conditions which require separate searches of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2 and 3 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Applicants are advised that

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1647

2) If applicant elects Invention III, there are three separate election of species requirements:

This application contains claims directed to the following patentably distinct species:

(i) Species of "action", as listed in claim 10: blocking an interaction between LL-37 and its receptor, blocking an intracellular signal, blocking an intracellular signal cascade, and blocking growth of arteries.

(ii) Species of agent, as listed in claims 12 and 13: anti-LL-37 antibody, anti-LL-37 receptor antibody, non-stimulatory form of LL-37, soluble form of LL-37 receptor, other peptide or polypeptide, nucleic acid, small organic compound, ligand, hormone, peptide nucleic acid, and peptidomimetic.

The species are independent or distinct because they are structurally and functionally distinct compounds that require separate search of the art, and would present an undue search burden.

(iii) Species of tumor, as listed in claim 18, including specification of either carcinoma or sarcoma, as well as whether the cancer is of the bile duct, brain, breast, colon, stomach, male reproductive organs, female reproductive organs, lung and airways, skin, gallbladder, liver, nasopharynx, nerve cells, kidney, prostate, or is Kaposi's sarcoma.

The species are independent or distinct because they are structurally and biologically distinct tumors that require separate search of the art, and would present an undue search burden.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species *for each of election requirements (i), (ii) and (iii)* for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 9 and 14 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected for each of the three requirements above, consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

Art Unit: 1647

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner